IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

FRANCIS KEMP,	)	CASE NO. _____
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	**COMPLAINT and JURY DEMAND**
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., and BOEHRINGER INGELHEIM INTERNATIONAL GMBH,	)	
	)	
Defendants.	)	

COMES NOW Plaintiff, Francis Kemp, by and through his attorneys, and brings this action for personal injuries suffered as a proximate result of Plaintiff being prescribed and ingesting the defective and unreasonably dangerous drug Pradaxa™ (dabigatran etexilate), a prescription medication used as a blood thinner, which at all times relevant hereto, was manufactured, designed, tested, packaged, labeled, marketed, advertised, distributed, and sold by Defendants Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim International GmbH (collectively, "Boehringer Ingelheim" or "Defendants"). For his complaint, Plaintiff alleges as follows:

PARTIES

1. At all times relevant hereto, Plaintiff, Francis Kemp, was and is a resident and citizen of Nebraska.

2. Defendant Boehringer Ingelheim Pharmaceuticals, Inc., ("Boehringer US") is a corporation organized under Delaware law, which has its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Boehringer US may be served at 900 Ridgebury

Road, Ridgefield, Connecticut 06877. Boehringer US has conducted business and derived substantial revenue from within the State of Nebraska.

3. Defendant Boehringer Ingelheim International GmbH ("Boehringer International") is a foreign corporation with its principal place of business located at Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany. Boehringer International has transacted and conducted business within the State of Nebraska. Boehringer International has derived substantial revenue from goods and products disseminated and used in the State of Nebraska, and Boehringer International expected or should have expected their acts to have consequences within the State of Nebraska, and derived substantial revenue from commerce within the State of Nebraska.

JURISDICTION AND VENUE

4. Jurisdiction is proper in this court pursuant to 28 U.S.C. § 1332 for the reason that there is complete diversity of citizenship between Plaintiffs and Defendants and the matter in controversy greatly exceeds the sum of seventy-five thousand dollars ($75,000.00), exclusive of interest and costs.

5. This Court has jurisdiction over the non-resident Defendants because they have done business in the State of Nebraska, have committed a tort in whole or in part in the State of Nebraska, and have continuing contacts with the State of Nebraska.

6. Venue of this case is proper in the District of Nebraska pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims occurred, in part, in the District of Nebraska.

STATEMENT OF FACTS

7. Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted, labeled, tested and sold Pradaxa™ as a blood-thinning medicine primarily used to reduce the risk of stroke and blood clots in people with atrial fibrillation not caused by a heart valve problem.

8. Pradaxa™ was launched by Defendants in North America in 2010.

9. Pradaxa™ was approved by the Food and Drug Administration ("FDA") in October of 2010 for prevention of stroke in patients with non-valvular atrial fibrillation. Pradaxa™ is the first new treatment alternative to warfarin (Coumadin) in nearly 60 years.

10. According to the Defendants' marketing and informational materials, referenced in the paragraphs below, and widely disseminated to the consuming public, atrial fibrillation ("AF") is the most common sustained heart rhythm condition in the world, with one in four adults over the age of 40 developing the condition in their lifetime.[1]

11. As the Defendants state on their website, "[AF] is a type of irregular heartbeat. It occurs when one or both of the upper chambers of the heart -- called the atria -- beat erratically. This puts them out of sync with the heart's 2 lower chambers -- called the ventricles."[2] Because the atria are primer pumps for the two large ventricles, AF normally causes only a modest reduction in cardiac output. But in the "dead zone" of the malfunctioning atria, blood clots may form and then travel to the lungs or brain, where irreversible and potentially life-threatening damage may occur.[3]

[1] http://www.boehringer-ingelheim.com/news/news_releases/press_releases/2011/04_aug_2011_dabigatran.html.
[2] http://www.pradaxa.com/understanding-afib.jsp.
[3] Institute for Safe Medication Practices, *QuarterWatch Report*, January 12, 2012.

12. The Defendants claim that approximately one percent of the total population is affected by AF worldwide, or approximately 70+ million people in the world, and more than 2 million people in the United States alone have AF. AF is a disease that typically has an impact on aging populations, and indeed, its prevalence increases with age.

13. While some cases of AF have no apparent or known cause, various conditions and/or lifestyle factors are believed to trigger or increase the odds of developing AF. For example, the following are believed to trigger AF in adults: high blood pressure; being obese or overweight; diabetes; having an overactive thyroid gland; lung cancer; and drinking too much alcohol or binge drinking.

14. Defendants posit that AF is not a directly life-threatening condition, but in their marketing materials, Defendants state that AF can have serious and even deadly consequences for patients.

15. Defendants further declare that patients with AF are more likely to experience the development of a blood clot in their heart, especially if their condition is left untreated. If such a clot were to form, the blood clot could break loose, and after breaking loose, the clot can be washed into the brain, where it can block an artery and cause a stroke. Defendants state that patients with AF thus "have a five-fold increased risk of stroke when compared to people without atrial fibrillation. Up to three million people worldwide suffer strokes related to AF each year. Strokes due to AF tend to be severe, with an increased likelihood of death and disability."[4] 16.

Defendants claim their medication, Pradaxa™, is the answer to the worldwide problem of strokes and blood clots in those with AF. They claim, "Many AF-related strokes can be prevented

[4] http://www.boehringer-ingelheim.com/products/prescription_medicines/stroke_prevention.html.

with appropriate medicinal therapy. For this, substances are used which act on the blood clotting system and shall prevent blood clots from forming."[5]

17. Historically, conditions such as AF have been treated with the prescription drug warfarin, which is a form of rat poison. Warfarin blocks the formation of the tiny fibrin threads that help hold together the platelets that collect in a person's blood to form a blood clot. Like all blood thinners, warfarin can cause bleeds. Warfarin has two other noteworthy limitations: (1) it requires blood tests every 1 to 4 weeks to establish the optimal level of anticoagulation, and (2) it interacts (negatively) with scores of other drugs, including drugs frequently used in heart patients. In spite of these apparent limitations; however, warfarin also has an important benefit; if an overdose or unexpected bleed occurs, an antidote (e.g., vitamin K) is readily available and highly effective.[6]

18. Pradaxa™ is administered as an oral anticoagulant and is from the class of the direct thrombin inhibitors ("DTI").

19. According to the Defendants' website, Pradaxa™ is "at the forefront of a new generation of oral blood thinning treatments, which prevent blood clots from forming in the body that can lead to devastating strokes in patients with atrial fibrillation. Potent antithrombotic effects are achieved with DTIs by specifically blocking the activity of thrombin (both free and clot-bound), the central enzyme in the process responsible for thrombus formation."[7]

20. According to Defendants testing and marketing materials, which extol the supposed benefits and virtues of Pradaxa™, Pradaxa™ had fewer drug interactions than warfarin, and the frequent laboratory tests needed to manage warfarin blood levels were not recommended for

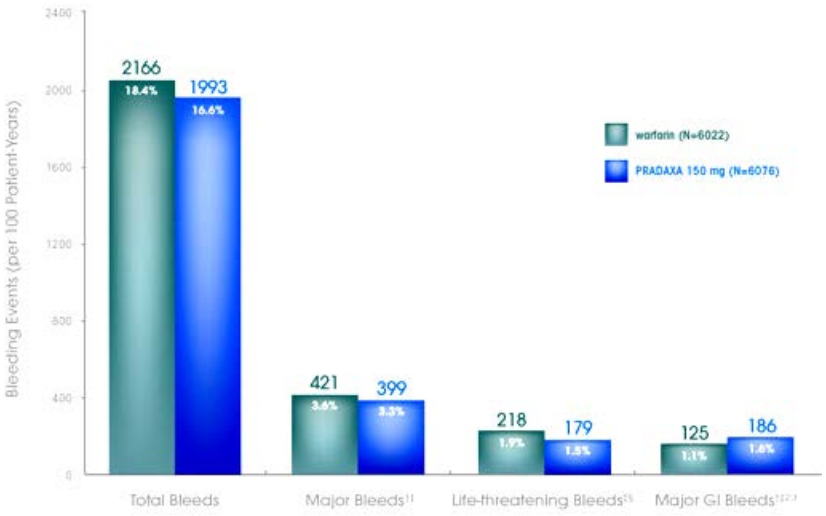
[5] *Id.*
[6] Institute for Safe Medication Practices, *QuarterWatch Report*, January 12, 2012.
[7] http://www.boehringer-ingelheim.com/products/prescription_medicines/stroke_prevention.html.

patients taking Pradaxa™. Moreover, unlike warfarin, which is adjusted for individual patient blood levels on an ongoing basis, Pradaxa™ was approved in an allegedly easy "one size fits all" dose of 150 mg twice a day. This "one size fits all" characteristic of the drug, while simple for physicians to follow, means that a lower (or personalized) dose is unavailable and patients ingesting Pradaxa™ are not routinely monitored to see if they are getting too much of the drug's active ingredient, as are patients on other blood thinning medications like warfarin.

21. Moreover, the "RE-LY Clinical Trial" (Randomized Evaluation of Longterm anticoagulant therapy) sponsored by Defendants concluded that vitamin K antagonists such as warfarin are cumbersome to use because of their multiple interactions with food and drugs and because these drugs require frequent laboratory monitoring.

22. The RE-LY Clinical Trial went on to suggest that there is a need for new anticoagulant agents that are effective, safe, and convenient to use (i.e., Defendants' product, Pradaxa™). The Defendants' marketing materials suggest that Pradaxa™ represented a therapeutic simplification and therapeutic progress because it does not require patients to undergo periodic monitoring with blood tests. A fundamental tenet of the RE-LY Clinical Trial was a claim by Defendants that Pradaxa™ was apparently safe to use as compared to warfarin. As the Defendants highlight on their website in claiming Pradaxa™ generally has similar, but lower overall total bleeds vs. warfarin[8]:

[8] http://www.pradaxapro.com/safety.jsp.



23. What the RE-LY Clinical Trial seemed to prove was quite simple: With Pradaxa™ there is (1) a higher rate of major GI bleeds (1.6% vs 1.1%) as compared to warfarin; and (2) a similar rate of major bleeds (3.3% vs 3.6%) as compared to warfarin. Additionally, Pradaxa™ appears to be particularly dangerous when used in older patients, as the label states: "The risk of major bleeds was similar with PRADAXA 150mg and warfarin across major subgroups defined by baseline characteristics, with the exception of age, where there was a trend towards a higher incidence of major bleeding on PRADAXA (HR 1.2, 95% CI: 1.0 to 1.4) for patients •75 years of age."[9] In spite of this reference regarding age, the label is still wholly inadequate because, among other reasons, this information was not conveyed in the warnings section.

24. In essence, the Defendants have created a new drug, Pradaxa™, that is no better than warfarin from a safety perspective, and at best, perhaps slightly easier to use and administer. The idea of this apparently easier-to-use anticoagulant evidently appealed to physicians, who were subject to extreme marketing and promotion by the Defendants, but it ignores patient safety.

[9] http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022512s009lbl.pdf.

25. On February 14, 2011, the American College of Cardiology Foundation and American Heart Association added Pradaxa™ to their guidelines for management of non-valvular atrial fibrillation with a "Class I" recommendation. The endorsement, along with heavy marketing from the Defendants, caused sales of Pradaxa to skyrocket. By the end of the first quarter of 2011, IMS Health's National Prescription Audit data showed 272,119 dispensed outpatient prescriptions. But, as prescriptions mounted, reports of serious adverse drug events also surged.[10]

26. As a result of the defective nature of Pradaxa™, persons who were prescribed and ingested Pradaxa™ for even a brief period of time, including Plaintiff herein, were at increased risk for developing life-threatening bleeds. Due to the flawed formulation of Pradaxa™ (and unlike any of the traditional blood thinners on the market, Pradaxa™ has a questionable "one size fits all" dose), its levels in the blood are difficult or impossible to assess and bleeds cannot be stopped since there is no known reversal antidote for this dangerous drug.

27. In November 2011, Defendants confirmed at least 260 fatal bleeding events were reported in patients taking Pradaxa™ worldwide between March 2008 and October 2011. The actual number of Pradaxa ™ related deaths remains unknown at this time. Moreover, the Institute for Safe Medication Practices reported that:

> In the first quarter of 2011 [Pradaxa™] produced two different kinds of signals of major drug risk: a large volume of total serious reports, and large numbers of reports for a specific adverse event, hemorrhage. Overall [the study] identified 932 serious adverse drug events of all types in which [Pradaxa™] was the primary suspect drug, including 120 patient deaths, 25 cases of permanent disability, and 543 cases requiring hospitalization. For the quarter, this was a higher total than for any drug [the Institute for Safe Medication Practices] monitor[s] with one exception. In the Standardized MedDRA Query ("SMQ") for Hemorrhage, [Pradaxa™] accounted for 505 cases, more than any other drug. (Warfarin ranked second with 176 cases.) The 932 overall [Pradaxa™] cases in the first quarter [of 2011] included 293 cases that were also classified in the narrower gastrointestinal hemorrhage SMQ, more than any other regularly monitored drug. An additional 120 cases contained event terms in the Hemorrhagic stroke SMQ. The strokes are

[10] Institute for Safe Medication Practices, *QuarterWatch Report*, January 12, 2012.

> of particular concern because if treatment intended to prevent ischemic strokes then causes hemorrhagic strokes the risk/benefit balance is called into fundamental question. In 65 hemorrhage cases overall, the patients died.[11]

In other words, the deadly consequences of Pradaxa™ use did not go unnoticed.

28. On December 7, 2011, the FDA initiated an investigation into serious bleeding events associated with Pradaxa™ stating that the "FDA is working to determine whether the reports of bleeding in patients taking Pradaxa are occurring more commonly than would be expected, based on observations in the large clinical trial that supported the approval of Pradaxa [RE-LY trial]."

29. Defendants concealed their knowledge that Pradaxa™ can cause life-threatening, irreversible bleeds from Plaintiff, other consumers, the general public, and the medical community. Indeed, the Defendants did not warn of the irreversible nature of Pradaxa™ in the "Warnings and Precautions" section of the products initial warning label. The only warnings provided by Defendants were as follows:

----------WARNINGS AND PRECAUTIONS----------

- Risk of bleeding: PRADAXA can cause serious and, sometimes, fatal bleeding. Promptly evaluate signs and symptoms of blood loss. (5.1)
- Temporary discontinuation: Avoid lapses in therapy to minimize risk of stroke (5.2)
- P-gp inducers and inhibitors: Avoid coadministration of rifampin with PRADAXA because of effects on dabigatran exposure (5.3)

30. Specifically, Defendants did not adequately inform consumers and the prescribing medical community about the risks of uncontrollable bleeds associated with Pradaxa™ usage, nor did Defendants warn or otherwise advise on how to intervene and stabilize a patient should a bleed occur. Even in the expanded "Warnings and Precautions" section of the initial label only the following meager and unacceptably inadequate information was given:

[11] Institute for Safe Medication Practices, *QuarterWatch Report*, January 12, 2012.

5 WARNINGS AND PRECAUTIONS

5.1 Risk of Bleeding

PRADAXA increases the risk of bleeding and can cause significant and, sometimes, fatal bleeding. Risk factors for bleeding include the use of drugs that increase the risk of bleeding in general (e.g., anti-platelet agents, heparin, fibrinolytic therapy, and chronic use of NSAIDs) and labor and delivery. Promptly evaluate any signs or symptoms of blood loss (e.g., a drop in hemoglobin and/or hematocrit or hypotension). Discontinue PRADAXA in patients with active pathological bleeding.

In the RE-LY (Randomized Evaluation of Long-term Anticoagulant Therapy) study, a life-threatening bleed (bleeding that met one or more of the following criteria: fatal, symptomatic intracranial, reduction in hemoglobin of at least 5 grams per deciliter, transfusion of at least 4 units of blood, associated with hypotension requiring the use of intravenous inotropic agents, or necessitating surgical intervention) occurred at an annualized rate of 1.5% and 1.8% for PRADAXA 150 mg and warfarin, respectively *[see Adverse Reactions (6.1)]*.

31. In fact, the only section of Defendants original label that references the fact that Pradaxa™ has no known "reversal agent" is buried in section 10 of the "Full Prescribing Information" section of the Pradaxa™ label, which discusses "Overdosage" on the medication. The language in section 10 is effectively no warning at all as the "warning" is both inadequate and misplaced, as shown below:

10 OVERDOSAGE

Accidental overdose may lead to hemorrhagic complications. There is no reversal agent for dabigatran. In the event of hemorrhagic complications, initiate appropriate clinical support, discontinue treatment with PRADAXA, and investigate the source of bleeding. Dabigatran is primarily excreted in the urine and shows low plasma protein binding. Therefore, dabigatran can be dialyzed with the removal of about 60% of drug over 2 to 3 hours; however, data supporting this approach are limited. Measurement of aPTT or ECT may help guide therapy *[see Warnings and Precautions (5.1) and Clinical Pharmacology (12.2)]*.

32. Finally, in January of 2012, after thousands of Pradaxa™ users had been killed or injured as a result of their ingestion of Pradaxa™, the Defendants belatedly initiated an extremely modest, and wholly inadequate, label change.

33. Importantly, Pradaxa™ still does not have a "black box" warning letting patients or their prescribing doctors know that Pradaxa™ can cause sudden and irreversible bleeds. Indeed, the relevant part of the "Warnings and Precautions" section itself remains unchanged (with no reference to the irreversible nature of Pradaxa™ bleeds) on the current Pradaxa™ label as shown below:

----------WARNINGS AND PRECAUTIONS----------

- Risk of bleeding: PRADAXA can cause serious and, sometimes, fatal bleeding. Promptly evaluate signs and symptoms of blood loss. (5.1)
- Temporary discontinuation: Avoid lapses in therapy to minimize risk of stroke (5.2)
- P-gp inducers and inhibitors: Effects on dabigatran exposure (5.3)

34. The only labeling modification Defendants made in January 2012 regarding the irreversible nature of Pradaxa™ bleeds was made in the "Warnings and Precautions" part of the

"Full Prescribing Information" section of the Pradaxa™ label, buried in small print on the fifth and sixth pages of the label. It reads:

5 WARNINGS AND PRECAUTIONS

5.1 Risk of Bleeding

PRADAXA increases the risk of bleeding and can cause significant and, sometimes, fatal bleeding. Promptly evaluate any signs or symptoms of blood loss (e.g., a drop in hemoglobin and/or hematocrit or hypotension). Discontinue PRADAXA in patients with active pathological bleeding *[see Dosage and Administration (2.2)]*.

ference ID: 3069855

Risk factors for bleeding include the use of other drugs that increase the risk of bleeding (e.g., anti-platelet agents, heparin, fibrinolytic therapy, and chronic use of NSAIDs). PRADAXA's anticoagulant activity and half-life are increased in patients with renal impairment *[see Clinical Pharmacology (12.2)]*

A specific reversal agent for dabigatran is not available. Dabigatran can be dialyzed (protein binding is low, with the removal of about 60% of drug over 2-3 hours); however the amount of data supporting this approach is limited. Activated prothrombin complex concentrates (aPCCs, e.g., FEIBA), or recombinant Factor VIIa, or concentrates of coagulation factors II, IX or X may be considered but their use has not been evaluated in clinical trials. Protamine sulfate and vitamin K are not expected to affect the anticoagulant activity of dabigatran. Consider administration of platelet concentrates in cases where thrombocytopenia is present or long-acting antiplatelet drugs have been used.

35. The current warning is simply inadequate. The Defendants have failed and continue to fail in their duties to warn and protect the consuming public, including the Plaintiff herein.

36. Even if the warnings were sufficient, which Plaintiff strongly denies, Pradaxa™ still lacks any benefit sufficient to tolerate the extreme risk posed by the ingestion of this drug. Pradaxa™ is quite simply dangerous and defective as formulated. The Defendants should withdraw Pradaxa™ from the market.

37. Indeed, a FDA analysis showed that with Pradaxa™ treatment, life-threatening bleeds (a drug adverse effect) occurred at a higher rate than the strokes or systemic embolisms Pradaxa™ is intended to prevent (1.5% per year versus 1.1% a year), suggesting that Pradaxa™ creates an extreme risk for patients and provides no benefit whatsoever.[12] Pradaxa™, under the guise of providing a safe defense against strokes and/or embolisms in AF patients, subjects unsuspecting patients to new dangers of death and injury.

[12] Institute for Safe Medication Practices, *QuarterWatch Report*, January 12, 2012.

38. Defendants willfully, wantonly and with malice withheld the knowledge of increased risk of irreversible bleeds in users of Pradaxa™ to prevent any chances of their product's registrations being delayed or rejected by FDA.

39. As the manufacturers and distributors of Pradaxa™, Defendants knew or should have known that Pradaxa™ use was associated with irreversible bleeds.

40. With the knowledge of the true relationship between use of Pradaxa™ and irreversible bleeds, rather than taking steps to pull the drug off the market, provide strong warnings, or create an antidote, Defendants promoted and continue to promote Pradaxa™ as a safe and effective treatment for AF and alternative to warfarin.

41. Pradaxa™ is expected to be one of Defendants' top-selling drugs. Upon information and belief, Defendants "expect[s] sales of blood thinner Pradaxa to reach 450 million euros ($603 million) this year."[13]

42. While Defendants enjoy great financial success from their expected blockbuster drug, Pradaxa™, they continue to place American citizens at risk of severe bleeds and death.

43. Consumers, including Plaintiff, who have used Pradaxa™ for treatment of AF and blood thinning, have several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits, associated with Pradaxa™ therapy.

44. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with Pradaxa™ use.

[13] http://www.bloomberg.com/news/2011-11-28/boehringer-expects-2011-pradaxa-sales-of-603-million-dpasays.html.

45. As a result of Defendants' actions, Plaintiff and Plaintiff's physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff would be exposed to the risks identified in this Complaint. The increased risks and subsequent medical damages associated with Plaintiff's Pradaxa ™ use were the direct and proximate result of Defendants' conduct.

46. On or about October 14, 2013, Plaintiff Francis Kemp was first prescribed and began taking Pradaxa™ upon direction of Plaintiff's physician for long-term maintenance of Plaintiff's AF. Subsequently, as a direct result of Plaintiff's ingestion of Pradaxa™, Plaintiff suffered a major internal hemorrhage on November 22, 2014, whereupon Plaintiff nearly bled to death. Plaintiff was admitted to intensive care and spent several days at the Good Samaritan Hospital in Kearney, Nebraska, where Plaintiff received multiple blood transfusions and other treatment and Pradaxa™ was discontinued.

47. As a proximate result of Defendants' acts and omissions, Plaintiff suffered the injuries described hereinabove due to Plaintiff's ingestion of Pradaxa™. Plaintiff accordingly seeks damages associated with these injuries.

48. Plaintiff would not have used Pradaxa™ had Defendants properly disclosed the risks associated with its use.

CLAIMS FOR RELIEF

COUNT I
STRICT LIABILITY – FAILURE TO WARN

49. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

50. Defendants are liable under the theory of strict products liability. Defendants were at all times relevant to this suit, and are now, engaged in the business of designing, manufacturing,

testing, marketing, and placing into the stream of commerce pharmaceuticals for sale to, and use by, members of the public, including the Pradaxa™ at issue in this lawsuit. The Pradaxa™ manufactured by Defendants reached Plaintiff without substantial change and was ingested as directed. The Pradaxa™ was defective and unreasonably dangerous when it entered into the stream of commerce and when used by Plaintiff.

51. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known that warnings and other clinically relevant information and data which they distributed regarding the risks of irreversible bleeds and other injuries and death associated with the use of Pradaxa™ were inadequate.

52. Plaintiff did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Plaintiff or to Plaintiff's treating physicians.

53. Defendants had a continuing duty to provide consumers, including Plaintiff and Plaintiff's physicians, with warnings and other clinically relevant information and data regarding the risks and dangers associated with Pradaxa™, as it became or could have become available to Defendants.

54. Defendants marketed, promoted, distributed and sold an unreasonably dangerous and defective prescription drug, Pradaxa™, to health care providers empowered to prescribe and dispense Pradaxa™ to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data. Through both omission and affirmative misstatements, Defendants misled the medical community and consumers about the risk and benefit balance of Pradaxa™, which resulted in injury to Plaintiff.

55. Despite the fact that Defendants knew or should have known that Pradaxa™ caused unreasonable and dangerous side effects, they continued to promote and market Pradaxa™ without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

56. Defendants knew or should have known that consumers, Plaintiff specifically, would foreseeably and needlessly suffer injury or death as a result of Defendants' failure to warn.

57. Defendants failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Plaintiff and to Plaintiff's intermediary physicians, in the following ways:

a. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff and Plaintiff's physicians to the dangerous risks of Pradaxa™ including, among other things, irreversible bleeds;

b. Defendants failed to provide adequate post-marketing warnings and instructions after the Defendants knew or should have known of the significant risks of, among other things, irreversible bleeds;

c. Defendants continued to aggressively promote and sell Pradaxa™, even after they knew or should have known of the unreasonable risks of irreversible bleeds from this drug.

58. Defendants had an obligation to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Pradaxa™, and/or that there existed safer and more or equally effective alternative drug products.

59. By failing to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Pradaxa™, and/or that there existed safer and more or equally effective alternative drug products, Defendants breached their duty of reasonable care and safety.

60. Defendants' actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of the Plaintiff and the public.

61. Defendants' actions described above violated the federal and state Food, Drug and Cosmetic Acts and rendered Pradaxa™ misbranded.

62. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Plaintiff was exposed to Pradaxa™ and suffered the injuries and damages set forth hereinabove.

COUNT II
STRICT LIABILITY – DESIGN DEFECT

63. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

64. At all times material to this action, Defendants were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling to its distributors and otherwise putting Pradaxa™ into the stream of commerce.

65. Pradaxa™ is defective and unreasonably dangerous to consumers.

66. Pradaxa™ is defective in its design and/or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

67. At all times material to this action, Pradaxa™ was expected to reach, and did reach, consumers throughout the United States, including Plaintiff herein, without any significant change in the condition in which Pradaxa™ was sold.

68. At all times material to this action, Pradaxa™ was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold to its distributors and otherwise put into the stream of commerce by Defendants in a defective and

unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, Pradaxa™ contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of Pradaxa™, including but not limited to the risks of developing severe, irreversible bleeds, which cause serious, crippling injuries and even death in an unacceptably high number of its users;

b. When placed in the stream of commerce, Pradaxa™ was defective in formulation, making the use of Pradaxa™ more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the blood-thinning medications and similar drugs on the market for the prevention of stroke in patients with non-valvular AF;

c. The design defects in Pradaxa™ existed before the product left the control of the Defendants;

d. Pradaxa™ was insufficiently tested;

e. Pradaxa™ causes harmful side effects that outweighed any potential utility;

f. Pradaxa™ is not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff herein, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff, individually and collectively; and

g. Pradaxa™ is not accompanied by adequate instructions and/or warnings to fully apprise physicians of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff, individually and collectively.

69. In addition, at the time Pradaxa™ left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible, and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the utility of Pradaxa™.

70. In addition, at the time Pradaxa™ left the control of Defendants there were practical and feasible alternative formulations that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of Pradaxa™. These safer alternative formulations were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the utility of Pradaxa™.

71. As the proximate cause and legal result of the defective condition of Pradaxa™ as designed and/or manufactured and/or supplied and/or distributed by Defendants and as a direct and legal result of the conduct of Defendants described herein, Plaintiff has been damaged.

COUNT III
NEGLIGENCE

72. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

73. Defendants owed a duty to the general public and specifically to the Plaintiff to exercise reasonable care in the design, study, development, manufacture, promotion, sale, marketing and distribution of their prescription medications, including the Pradaxa™ at issue in this lawsuit. Defendants failed to exercise reasonable care in the design of Pradaxa™ because as designed, it was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use. Defendants also failed to exercise reasonable care in the marketing of Pradaxa™ because they failed to warn, that as designed, Pradaxa™ was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use.

74. Defendants breached their duty and were negligent by, but not limited to, the following actions, misrepresentations, and omissions toward Plaintiffs:

a. Failing to use due care in developing, testing, designing and manufacturing Pradaxa™ so as to avoid the aforementioned risks to individuals when Pradaxa™ was being used for treatment;

b. Failing to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of Pradaxa™ and the comparative severity and duration of such adverse effects;

c. In disseminating information to Plaintiff and Plaintiff's physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff;

d. Failing to accompany their products with proper or adequate rate of incidence or prevalence of irreversible bleeds;

e. Failing to provide warnings or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks;

f. Failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Pradaxa™;

g. Failing to warn Plaintiff, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative medications available to Plaintiff and other consumers;

h. Failing to provide adequate training or information to medical care providers for appropriate use and handling of Pradaxa™ and patients taking Pradaxa™;

i. Failing adequately to test and/or warn about the use of Pradaxa™, including, without limitations, the possible adverse side effects and health risks caused by the use of Pradaxa™;

j. Failing to design and/or manufacture a product that could be used safely due to the lack of a known reversal agent or antidote;

k. In designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable use, which Defendants knew or should have known could cause injury to Plaintiff;

l. Failing to remove Pradaxa™ from the market when Defendants knew or should have known of the likelihood of serious side effects and injury to its users;

m. Failing to adequately warn users, consumers and physicians about the severity, scope and likelihood of bleeds and related dangerous conditions to individuals taking Pradaxa™; and

n. Representing to physicians, including but not limited to Plaintiff's prescribing physicians, that this drug was safe and effective for use.

75. The Pradaxa™ that injured Plaintiff was in substantially the same condition when Plaintiff ingested it as it was in when it left the control of Defendants. Pradaxa's™ ability to cause serious personal injuries and damages such as those suffered by Plaintiff was not due to any voluntary action or contributory negligence of Plaintiff. Plaintiff consumed the Pradaxa™ as directed and without change in its form or substance.

76. Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Pradaxa™ was a proximate cause of Plaintiff's injuries and damages.

77. Plaintiff seeks all damages to which Plaintiff may be justly entitled.

COUNT IV
NEGLIGENCE PER SE

78. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

79. As part of their duty to exercise reasonable care, Defendants were obliged to follow public laws and regulations enacted and promulgated to protect the safety of persons such as Plaintiff, including 21 U.S.C. §§ 331(a) & 352, and other statutes and regulations, which make it unlawful to misbrand prescription drug products.

80. The labeling, including package inserts, for Pradaxa™ failed to conform to the requirements of 21 U.S.C. § 352, including subsections (a), (c), and (f), and the requirements of 21 C.F.R. § 201.100(c)(1), and, therefore, violated 21 U.S.C. § 331(a), which prohibits "[t]he

introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."

81. Specifically, the product label and package insert for Pradaxa™ is misbranded within the meaning of 21 U.S.C. § 352(a) and (f) because it was false and misleading and failed to give adequate warnings and directions for use by physicians who prescribe Pradaxa™.

82. Pradaxa™ is misbranded pursuant to 21 U.S.C. § 352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

83. Pradaxa™ is misbranded pursuant to 21 U.S.C. § 352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

84. Pradaxa™ is misbranded pursuant to 21 U.S.C. § 352 because it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

85. Because the Defendants each had a statutory duty under 21 U.S.C. § 352(a) and (f) not to misbrand Pradaxa™, and because each of them violated this duty, they were guilty of negligence per se.

86. Pradaxa™ is further misbranded pursuant to 21 C.F.R. § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

87. Defendants also violated 21 C.F.R. § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug Pradaxa™.

88. Defendants violated 21 C.F.R. § 201.57 because the safety considerations regarding Pradaxa™ are such that the drug should be reserved for certain situations, and the Defendants failed to state such information.

89. Pradaxa™ is mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur.

90. Pradaxa™ is mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug (i.e., irreversible bleeding).

91. Pradaxa™ is mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling does not state an upper limit dosing beyond which safety and effectiveness have not been established.

92. Pradaxa™ violates 21 C.F.R. § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

93. Pradaxa™ violates 21 C.F.R. § 310.303 in that it is not safe and effective for its intended use.

94. Defendants violated 21 C.F.R. §§ 310.305 & 314.80 by failing to report adverse events associated with Pradaxa™ as soon as possible or at least within 15 days of the initial receipt by the Defendants of notice of the adverse drug experiences.

95. Defendants violated 21 C.F.R. §§ 310.305 & 314.80 by failing to conduct an investigation of each adverse event associated with Pradaxa™, evaluate the cause of the adverse event, submit follow-up reports within the prescribed 15 calendar days of receipt of new

information or as requested by the FDA, and keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

96. Defendants violated 21 C.F.R. § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated) and/or (d) a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

97. Defendants violated 21 C.F.R. § 312.32 because they failed to review all information relevant to the safety of Pradaxa™ or otherwise received by Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

98. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff, making Defendants liable to Plaintiff, and further, because each of them violated the above-referenced duties required by these statutes and regulations, they are guilty of negligence per se

99. Defendants failure adequately to warn about the magnitude of the risk associated with use of Pradaxa™ constitutes negligence per se. This negligence per se proximately caused injury to Plaintiff as described more fully herein.

COUNT V
NEGLIGENT MISREPRESENTATION

100. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

101. The Pradaxa™ in question was originally formulated, designed, manufactured, marketed, and sold by Defendants.

102. At the time the Pradaxa™ in question was sold, Defendants were in the business of formulating, designing, manufacturing, marketing, and selling products such as the one in question and knew that it would be used without inspection for defects.

103. Defendants from the time that the Pradaxa™ at issue was first manufactured, marketed and distributed, and up to the present, made false misrepresentations, as previously set forth herein, to Plaintiff, Plaintiff's physicians, and the general public, including but not limited to, the misrepresentation that Pradaxa™ was safe, fit and effective for human use. At all times herein mentioned, the Defendants conducted a sales and marketing campaign to promote the sale of Pradaxa™ and willfully deceived Plaintiff, Plaintiff's physicians, and the general public as to the health risks and consequences of the use of Pradaxa™.

104. The Defendants made the foregoing representations without any reasonable ground for believing them to be true. These representations were made directly by the Defendants through their sales representatives and other authorized agents and in publications and other written materials directed to physicians and medical patients, with the intention of inducing reliance and the purchase and use of Pradaxa™ prescriptions. The foregoing representations by the Defendants were in fact false, in that Pradaxa™ was not safe, fit, and effective for human use, and the use of Pradaxa™ is hazardous to health and has a serious propensity to cause serious injuries, including death, to users.

105. The foregoing representations by the Defendants were made with the intention of inducing reliance and the prescription, purchase, and use of Pradaxa™.

106. In reliance on the misrepresentations by the Defendants, Plaintiff was induced to purchase and use Pradaxa™. If Plaintiff had known the true facts and the facts concealed by the Defendants Plaintiff would not have used Pradaxa™. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

107. As a result of said negligence and carelessness of Defendants, Plaintiff was caused to suffer the injuries described herein.

COUNT VI
FRAUD

108. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

109. Defendants committed actual fraud by making material representations, which were false, knowing that such representations were false and/or with reckless disregard for the truth or falsity of such representations, with the intent that Plaintiff rely on such material representations; Plaintiff acted in actual and justifiable reliance on such material misrepresentations and was injured as a result.

110. In addition, and in the alternative if necessary, Defendants knowingly omitted and downplayed material information, which omission constitutes a positive misrepresentation of material fact, with the intent that Plaintiff rely on Defendants' misrepresentations; Plaintiff acted in actual and justifiable reliance on Defendants' representations and was injured as a result.

111. Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiff relating to the Pradaxa™ at issue in this lawsuit, said breach or

breaches constituting fraud because of their propensity to deceive others or constitute an injury to public interests or public policy.

112. Defendants misrepresented to Plaintiff, and the health care industry the safety and effectiveness of Pradaxa™ and/or fraudulently, intentionally and/or negligently concealed material information, including adverse information regarding the safety and effectiveness of Pradaxa™.

113. Defendants made these misrepresentations and actively concealed adverse information at a time when the Defendants knew, or should have known, that Pradaxa™ had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff and the health care industry generally. Specifically, Defendants misrepresented to and/or actively concealed from Plaintiff and the consuming public that:

a. Pradaxa™ had statistically significant increases in irreversible bleeds and other side effects which could result in serious, permanent injury or death;

b. Pradaxa™ had not been fully or adequately tested;

c. Pradaxa™ does not have any known antidote and/or reversal agents;

d. Pradaxa™ bleeds cannot be stopped or controlled by any effective medical processes or medical intervention; and

e. Pradaxa™ was not as safe as blood thinners such as warfarin.

114. The misrepresentations of and/or active concealments alleged were perpetuated directly and/or indirectly by Defendants. Defendants knew or should have known that these representations were false and made the representations with the intent or purpose that Plaintiff and/or Plaintiff's prescribing physicians would rely on them, leading to the use of Pradaxa™. At the time of Defendants' fraudulent misrepresentations, Plaintiff and/or Plaintiff's prescribing physicians were unaware of the falsity of the statements being made and believed them to be true.

Plaintiff and/or Plaintiff's prescribing physicians had no knowledge of the information concealed and/or suppressed by Defendants, and they justifiably relied on and/or were induced by the misrepresentations and/or active concealment and relied on the absence of safety information, which Defendants did suppress, conceal or failed to disclose, to Plaintiff's detriment.

115. Defendants had a post-sale duty to warn Plaintiff, Plaintiff's prescribing and treating physicians, and the public about the potential risks and complications associated with Pradaxa™ in a timely manner. The misrepresentations and active fraudulent concealment by the Defendants constitute a continuing tort against Plaintiff, who purchased and/or ingested Pradaxa™. Defendants made the misrepresentations and actively concealed information about the defects and dangers of Pradaxa™ with the intention and specific desire that Plaintiff and the consuming public would rely on such or the absence of information in selecting Pradaxa™ as treatment.

116. As a direct and proximate result of the fraudulent acts and omissions, suppression, and misrepresentation of Defendants, Plaintiff suffered the injuries and damages discussed herein.

COUNT VII
BREACH OF WARRANTY – MERCHANTABILITY

117. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

118. Defendants were at the time of the acts forming the basis of this lawsuit, and now are, merchants with respect to the Pradaxa™ at issue in this lawsuit. Defendants have impliedly warranted to the public generally and specifically to Plaintiff that Pradaxa™ was merchantable and fit for safe use for preventing strokes and/or blood clots in patients with AF, the purpose for which Defendants marketed Pradaxa™. Pradaxa™ was not merchantable as warranted because, as designed, Pradaxa™ was capable of causing serious personal injuries such as those suffered

by Plaintiff during foreseeable use. Therefore, Defendants have breached the implied warranty of merchantability with respect to Pradaxa™.

119. As a direct and proximate result of Defendants' breach of the warranty of merchantability, Plaintiff sustained serious and permanent injuries and damages.

COUNT VIII
BREACH OF WARRANTY – FITNESS FOR A PARTICULAR PURPOSE

120. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

121. Defendants knew that consumers such as Plaintiff would require Pradaxa™ for safe use for treatment of AF, and that consumers would rely on Defendants' skill and judgment to select suitable medications. Defendants provided such skill and judgment by marketing and selling Pradaxa™ for that purpose. Plaintiff relied on Defendants' skill and judgment when selecting and purchasing the Pradaxa™ at issue. The Pradaxa™ used by Plaintiff was not fit for its particular purpose because, as designed, Pradaxa™ was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use. Therefore, Defendants have breached the implied warranty of fitness for a particular purpose with respect to Pradaxa™.

122. As a direct and proximate result of Defendants' breach of the warranty of fitness for a particular purpose, Plaintiff sustained the injuries and damages discussed herein.

COUNT IX
BREACH OF WARRANTY - EXPRESS WARRANTY

123. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

124. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of

commerce Pradaxa™, and in the course of same directly advertised or marketed the product to health care professionals and consumers, including Plaintiff.

125. Pradaxa™ materially failed to conform to those representations made by Defendants in package inserts, and otherwise, concerning the properties and effects of Pradaxa™, respectively manufactured and/or distributed and sold by Defendants, and which were relied upon by Plaintiff and Plaintiff's health care providers. Such failures by Defendants constituted a material breach of express warranties concerning Pradaxa™.

126. As a direct, foreseeable and proximate result of Defendants' breaches of express warranties, Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when Plaintiff's physician, in reasonable reliance upon such express warranties, prescribed for Plaintiff the use of Pradaxa™. Plaintiff purchased and ingested Pradaxa™ as prescribed and instructed by Plaintiff's physician, leading to Plaintiff's injuries.

COUNT X
INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

127. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

128. The acts, omissions, and representations of the Defendants regarding the manufacturing, distribution and marketing of Pradaxa™ as described in the foregoing paragraphs were intentional, reckless, extreme and outrageous. Defendants intentionally engaged in extreme and outrageous conduct when they intentionally and/or recklessly marketed Pradaxa™ and then intentionally and/or recklessly concealed material information about the potential serious adverse effects of Pradaxa™ from Plaintiff and from physicians, hospitals, and medical providers.

129. Defendants knew that Plaintiff would suffer mental distress and anxiety upon learning that Pradaxa™ possessed a likelihood of serious adverse effects and complications or

death from significant increased risk of irreversible bleeding, which was caused by Defendants' drug, Pradaxa™.

130. As a result of Defendants' misconduct, Plaintiff sustained emotional and mental distress and anxiety.

COUNT XI
NEGLIGENT INFLICITION O EMOTIONAL DISTRESS

131. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

132. Defendants negligently and carelessly manufactured, sold and distributed to Plaintiff Pradaxa™, which was defective.

133. Defendants negligently and carelessly concealed the defective nature of Pradaxa™ from Plaintiff, physicians, hospitals, and medical providers.

134. Defendants negligently and carelessly misrepresented the usefulness, quality and safety of Pradaxa™ to Plaintiff, physicians, hospitals, and medical providers.

135. The Defendants' negligence and carelessness directly impacted the Plaintiff in that Plaintiff was induced to purchase and ingest the defective and dangerous Pradaxa™.

136. As a direct result of Defendants' misconduct alleged herein, Plaintiff suffered emotional and mental distress and anxiety from the fear of knowing there is a likelihood of serious complications or death from significant increased risk of irreversible bleeding, which was caused by Defendants' drug, Pradaxa™.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that upon final determination of these causes of action Plaintiff receives a judgment against Defendants as follows:

a. Actual damages jointly and/or severally against Defendants, which include, but is not limited to, personal injuries and consequential damages, past and future expenses for necessary medical treatment, past and future loss of earnings, past and future pain and suffering, loss of earning capacity, and past and future loss of enjoyment of life, mental anguish and emotional distress,;

b. Punitive damages alleged against Defendants;

c. Costs of court and reasonable attorney fees necessary for preparation of this case for trial;

d. Prejudgment interest at the highest lawful rate allowed by law;

e. Interest on the judgment at the highest legal rate from the date of judgment until collected; and

f. All such other and further relief at law and in equity to which Plaintiff may show himself to be justly entitled.

DATED this 21st day of November, 2018.

FRANCIS KEMP, Plaintiff,

By: /s/ Christopher P. Welsh

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